

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MEDA PHARMACEUTICALS INC.,)

Plaintiff,)

vs.)

Civil Action No. 06-164-SLR

APOTEX INC. and APOTEX CORP.,)

Defendants.)

STIPULATED FINDINGS OF FACT

Plaintiff Meda Pharmaceuticals Inc. ("Meda") and Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex"), through their respective counsel, hereby stipulate as follows:

A. Meda is the sole owner of U.S. Patent No. 5,164,194 ("the '194 patent"). To the extent that the '194 patent is valid and enforceable, Meda has the right to sue and recover for any infringement of that patent.

B. Meda holds New Drug Application ("NDA") 20-114 on ASTELIN® brand azelastine hydrochloride nasal spray, which NDA was approved by the U.S. Food and Drug Administration ("FDA") on November 1, 1996.

C. Meda represents, and Apotex does not contest, that use of Meda's ASTELIN® brand azelastine hydrochloride nasal spray for the treatment of the symptoms of seasonal allergic rhinitis or the symptoms of vasomotor rhinitis falls within the scope of Claims

4, 5, 7, 8 and 9 of the '194 patent. Meda further represents, and Apotex does not contest, that U.S. sales of ASTELIN® have totaled over \$961 million from November 1996 through December 2007 and totaled over \$188 million during the twelve months ending December 31, 2007.

D. Apotex's filing of Abbreviated New Drug Application ("ANDA") 77-954 for a generic azelastine hydrochloride nasal spray, which ANDA included a Paragraph IV Certification under §505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, constitutes a technical act of infringement of the '194 patent pursuant to 35 U.S.C. §271(e)(2)(A). If commercially made, used, offered for sale or sold within the United States, or commercially imported into the United States, for the treatment of the symptoms of seasonal allergic rhinitis or the symptoms of vasomotor rhinitis, Apotex's proposed generic azelastine hydrochloride nasal spray would also literally infringe, induce literal infringement and/or contribute to literal infringement of Claims 4, 5, 7, 8 and 9 of the '194 patent to the extent that those claims are valid and enforceable.

E. These Stipulated Findings Of Fact should be without prejudice to any party's right to assert or rebut any defense or counterclaim that the '194 patent is invalid or unenforceable.

Based on the above stipulations, and in the interest of efficiency, judicial economy and other good cause shown, the Court hereby makes the following findings of fact:

1. Meda is the sole owner of the '194 patent. To the extent that the '194 patent is valid and enforceable, Meda has the right to sue and recover for any infringement of that patent.

2. Meda holds NDA 20-114 on ASTELIN® brand azelastine hydrochloride nasal spray, which NDA was approved by the U.S. FDA on November 1, 1996.

3. Use of Meda's ASTELIN® brand azelastine hydrochloride nasal spray for the treatment of the symptoms of seasonal allergic rhinitis or the symptoms of vasomotor rhinitis falls within the scope of Claims 4, 5, 7, 8 and 9 of the '194 patent. From November 1996 through December 2007, U.S. sales of ASTELIN® have totaled over \$961 million. During the twelve months ending December 31, 2007, U.S. sales of ASTELIN® totaled over \$188 million.

4. Apotex's filing of ANDA 77-954 for a generic azelastine hydrochloride nasal spray, which ANDA included a Paragraph IV Certification under §505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, constitutes a technical act of infringement of the '194 patent pursuant to 35 U.S.C. §271(e)(2)(A). If commercially made, used, offered for sale or sold within the United States, or commercially imported into the United States, for the treatment of the symptoms of seasonal allergic rhinitis or the symptoms of vasomotor rhinitis, Apotex's proposed generic azelastine hydrochloride nasal spray would also literally infringe, induce literal infringement and/or contribute to literal infringement of Claims 4, 5, 7, 8 and 9 of the '194 patent to the extent that those claims are valid and enforceable.


5. These Stipulated Findings Of Fact are without prejudice to any party's right to assert or rebut any defense or counterclaim that the '194 patent is invalid or unenforceable.

SO ORDERED:

This _____ day of _____, 2008.

HONORABLE SUE L. ROBINSON
UNITED STATES DISTRICT JUDGE

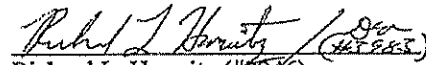
We hereby request and agree to entry of the foregoing Stipulated Findings Of Fact.


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